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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,255	11/27/2000	Kathleen E. Rodgers	00-448A	5684

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EXAMINER

CHISM, BILLY D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/03/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/723,255

Applicant(s)

RODGERS ET AL.

Examiner

B. Dell Chism

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10 and 16 is/are rejected.
- 7) ☒ Claim(s) 5, 11, 13 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Paper No. 10, filed 17 March 2003. The previous restriction/election requirement of a second compound from Group II of Set 1 is withdrawn and each compound was considered. Claims 12 and 14 are canceled and claims 1-11, 13 and 15-16 are pending.

Withdrawal of Objections and Rejections

The rejections and/or objections made in the prior office action, Paper No. 7 filed 10 September 2002, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. (Maintained) Claim 16 remains rejected under 35 U.S.C. 112, first paragraph,

because the specification, while being enabling for treatment of alopecia, does not

reasonably provide enablement for prevention of alopecia. For the reasons detailed in the previous office action, Paper No. 7, filed 10 September 2002, the claims remains rejected.

3. (New) Claims 1-4 and 6-9 are rejected under 35 U.S.C. 112, first paragraph,

because the specification, while being enabling for seven contiguous amino acids, i.e.,

SEQ ID NO: 41, does not reasonably provide enablement for compounds of 3, 4, 5 and 6

contiguous amino of General Formula I. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

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(1) *The nature of the invention:* The invention is drawn to a method of treating alopecia using a peptide sequence of at least three, four, five and six contiguous amino acids of general formula I (R1-R2-R3-R4-R5-R6-R7-R8).

(2) *The state of the prior art:* The art does not recognize the ability of peptides, similar to those claimed, to treat alopecia.

(3) *The relative skill of those in the art:* The relative skill of those in the art is high.

(4) *The predictability or unpredictability of the art:* As with all peptides in peptide chemistry, the activity of a peptide is dependent upon its structure and its ability to fold properly and/or recognize target sites as in pharmaceutical chemistry. It is known in the art that computer models assist in the research, but are not an absolute prediction tool for the activity of the compound. For example, in peptide chemistry, Ngo *et al.* teach that for proteins and peptides, a “‘Direct’ approach to structure prediction, that of directly simulating the folding process, is not yet possible because contemporary hardware falls eight to nine orders of magnitude short of the task.” (see page 493 in Ngo *et al.*).

Accordingly, it is not known if an efficient algorithm for predicting the structure exists for a protein or peptide from its amino acid alone (see page 492 in Ngo *et al.*). Similarly, the Science article also states that although computers can be used to design drugs, “for the most part technicians must still screen many, many compounds to find their magic bullets.” (see page 441 Ngo *et al.*). The article concludes that computer models are not an effective method of determining drug activity. “Even modest gains in the ability to predict drug activity from structural data will be enough to delight some computational biologist. “Developing drugs is a vague science in which you synthesize a

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large number of compounds.” (see page 441, Ngo *et al.*). Thus, without the ability of computers to accurately predict the function of a peptide structure with even a single amino acid difference from a known peptide structure, it is not possible for one of ordinary skill in the art to so.

(5) *The breadth of the claims*: The claims are broad. The claims define a general formula that has many possible sequence combinations that include L-amino acids, D-amino acids and other unnatural amino acids.

(6) *The amount of direction or guidance presented and (7) the presence or absence of working examples*: The specification states that the peptide compounds are for use in methods of treating alopecia. The specification also discloses sequences that fall within the scope of claim 1 that were found to be incapable of performing the claimed methods. Although, there are sequences disclosed that are 3, 4, 5 and 6 contiguous amino acid residues in length, there is no indication as to whether the compounds of that description contain/retain the core structure required to function as a structure is claimed to function for the treatment of alopecia. In fact, the disclosure shows that the contrary is true for sequences of 3, 4, 5 and 6 contiguous amino acid residues, that the sequences have no effect. The only guidance is found in the working examples, wherein the sequences were 7 amino acid residues in length.

(8) *The quantity of experimentation necessary*: Since it is unpredictable to state the efficacy of amino acids based solely on structure, and since there are amino acid sequences within the scope of the claims that possess 3, 4, 5 and 6 contiguous amino acid residues of the general formula I that were demonstrated to lack the ability to perform the claimed method, and since there is no defined required amino acid core for retention of

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efficacy, the quantity of experimentation necessary to make and/or use the claimed methods and compounds of the methods necessary for use of the invention, it would be an undue burden on one of skill in the art to require that person to determine which, of the 3, 4, 5 and 6 contiguous amino acid residues out of the many possible combinations of general formula I, would or would not demonstrate efficacy in the claimed method steps.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. (New) Claims 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-10 are rejected for the indefinite recitation of the phrase “consisting essentially of”, wherein it is not clear if the language is open or closed, or whether there are any affects on the basic and novel characteristics of the claimed invention by a compound that is within the scope of “consisting essentially of.”

Claim Objections

6. Claims 5, 11, 13 and 15 are objected for depending from rejected claim 1.

Conclusions

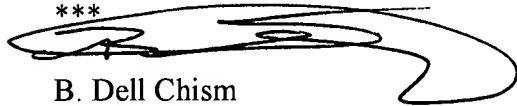
No claims are allowed. Claims 5, 11, 13 and 15 are objected for depending from rejected claim 1. Claims 1-4, 6-10 and 16 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



B. Dell Chism
02 June 2003


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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